K120744

510(k) Summary of Safety and Effectiveness

OCT 19 2012

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Deborah Kipp, Quality Assurance Coordinator
(402)537- 5215

Date Prepared: Revised-September 21, 2012

Name of Device:
Trade Name: XN CHECK™ BF
Common Name: Assayed Hematology Control
Classification Name: Hematology Quality Control Mixture-(JPK-864.8625)

Predicate Device: Cell-Chex Auto-K053362

Description:

XN CHECK™ BF is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s) and stabilized white blood cell component(s) in a preservative medium. The product is packaged in polypropylene plastic vials with screw caps containing 3 ml. The vials will be packaged in (4) welled vacuum formed clamshell container with the product information sheet / assay sheet. The product must be stored at 2 - 8° C.

Intended Use:

XN CHECK BF is used for control and calibration verification of Sysmex XN series (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters include:

WBC-BF (10^3/µl), RBC-BF (10^6/µl), MN# (10^3/µl), PMN# (10^3/µl), MN% (%), PMN% (%), TC-BF# (10^3/µl)

Comparison to Predicate Device:

	Cell-Chex™ Auto-K053362 (Predicate Product)	XN CHECK™ BF
Intended Use Statement	Cell-Chex Auto is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.	XN CHECK BF is used for control and calibration verification of Sysmex XN series (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters include: WBC-BF (10^3/µl), RBC-BF (10^6/ µl), MN# (10^3/µl), PMN# (10^3/µl), MN% (%), PMN% (%), TC-BF# (10^3/µl)
Open Vial Stability	30 days	Same
Closed Vial Stability	75 days	84 days
Reagents	Cell-Chex™ Auto contains stabilized human red blood cells and white blood cells in a preservative medium.	XN CHECK BF contains the following: stabilized red blood cell component(s) and stabilized white blood cell component(s) in a preservative medium.
Storage Conditions	2 - 10°C	2 - 8°C

Discussion of Tests and Test Results:
The following studies were conducted to establish performance of XN CHECK™ BF. The tests conducted were Open-Vial Stability, Closed-Vial Stability, and Precision Performance. All testing showed that XN CHECK™ BF is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests:
Study results show XN CHECK™ BF to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. XN CHECK™ BF is a safe and effective product, which fulfills its intended use when used as instructed in the Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 19 2012

Streck
c/o Ms. Deborah S. Kipp
Quality Assurance Coordinator
7002 South 109th Street
Omaha, NE 68128

Re: k120744
Trade/Device Name: XN-CHECK™ BF
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: September 28, 2012
Received: October 01, 2012

Dear Ms. Kipp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use Form

510(k) Number (if known): K120744

Device Name: XN CHECK™ BF

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Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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